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21171 STAAS & HAI	7590 01/19/200 LSEY LLP	EXAMINER		
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Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

	Application No.	Applicant(s)			
	10/624,567	MIYAHARA ET AL.			
Office Action Summary	Examiner	Art Unit			
	Robert T. Crow	1634			
The MAILING DATE of this communication appears on the cover sheet with the correspondence address Period for Reply					
A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION. - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication. - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication. - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).					
Status					
 Responsive to communication(s) filed on 12 October 2006. This action is FINAL. 2b) This action is non-final. Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213. 					
Disposition of Claims					
4) Claim(s) 1-9 and 11 is/are pending in the application 4a) Of the above claim(s) is/are withdraw 5) Claim(s) is/are allowed. 6) Claim(s) 1-9 and 11 is/are rejected. 7) Claim(s) is/are objected to. 8) Claim(s) are subject to restriction and/or	vn from consideration.				
Application Papers					
 9) The specification is objected to by the Examiner. 10) The drawing(s) filed on is/are: a) accepted or b) objected to by the Examiner. Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a). Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d). 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152. 					
Priority under 35 U.S.C. § 119					
 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) All b) Some * c) None of: Certified copies of the priority documents have been received. Certified copies of the priority documents have been received in Application No Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). * See the attached detailed Office action for a list of the certified copies not received. 					
Attachment(s)					
 Notice of References Cited (PTO-892) Notice of Draftsperson's Patent Drawing Review (PTO-948) Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date 11/2006 	4) Interview Summary Paper No(s)/Mail D 5) Notice of Informal F 6) Other:	ate			

FINAL ACTION

Status of the Claims

1. This action is in response to papers filed 12 October 2006 in which claims 1 and 11 were amended, claim 10 was canceled, and no new claims were added. All of the amendments have been thoroughly reviewed and entered.

The previous rejections under 35 U.S.C. 102(b) and 35 U.S.C. 103(a) not reiterated below are withdrawn in view of the amendments. Applicant's arguments have been thoroughly reviewed and are addressed following the rejections necessitated by the amendments.

The previous rejections under the judicially created doctrine of obviousness-type double patenting not reiterated below are withdrawn in view of the amendments. Applicant's arguments have been thoroughly reviewed and are addressed following the rejections necessitated by the amendments.

Claims 1-9 and 11 are under prosecution.

Claim Rejections - 35 USC § 112

- 2. The following is a quotation of the second paragraph of 35 U.S.C. 112:
 - The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.
- 3. Claims 1-9 and 11 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1-9 and 11 are indefinite in claim 1, which recites the limitation "when the chip is configured to be inserted and removed from the measuring apparatus" in lines 17-18 of claim 1. Line 12 of claim 1 requires the measuring apparatus to be a part of the chip; thus, it is unclear how the chip can be inserted and removed from itself. It is suggested that the claim be amended as to clarify the relationship between the chip and the measuring apparatus.

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Claim Rejections - 35 USC § 102

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4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

- (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
- 5. Claims 1 and 4-9 are rejected under 35 U.S.C. 102(b) as being anticipated by Heller et al (U.S. Patent No. 5,632,957, issued 27 May 1997).

Regarding claims 1, 4-6, Heller et al teach a detection chip. In a single exemplary embodiment, Heller et al teach a body having a depression; namely, a APEX chip (i.e., an active programmable electronic matrix hybridization system) having depressed microlocations in wells of an array (column 7, line 65-column 8, line 17 and Figure 2A). Heller et al also teach a containment structure that fits over the chip (column 15, lines 39-45 and Figure 9), which is an upper cover fixed to the body of the chip over the depressions. Heller et al further teach the chip is enclosed within a containment vessel (column 15, lines 5-45 and Figure 9), which forms an enclosed internal space part. The microlocations within the chip in the containment vessel are addressable by nucleic acids (Abstract) from human genes that are analyzed (column 10, line 61-column 11, line 3); thus, the depression is capable of being filled and emptied of gene samples. The nucleic acid attached (i.e., immobilized) at each microlocation is different (column 4, lines 55-60).

Heller et al teach that each of the plurality of microlocations has an electrode (column 8, lines 1-17), which are measuring electrodes. Heller et al also teach Figure 2B, which shows a single individual microlocation bearing a positive charge and the other microlocations bearing negative charges (column 8, lines 53-65); thus, one microlocation functions as a common electrode which is a counter electrode to the remaining measuring electrodes, and all of the microlocations are arranged in an array in the space part. Figure 2B also shows the counter electrode is not in contact with the other electrodes because it is in a

different well in the array. Heller et al also teach a measuring apparatus capable of detecting and analyzing genes; namely, the remainder of the system (Abstract) comprising a computer that measures currents, potentials, and results of assays (column 13, lines 1-4). Heller et al also teach voltammetry to detect DNA hybridization (column 19, lines 15-42), which is interpreted as measuring and detecting the voltage applied between the common and measuring electrodes.

Heller et al also teach the chip (i.e., the matrix hybridization region) is adapted for removal from the remainder of the device (column 6, lines 50-53), which is interpreted as being configured for insertion and removal from the measuring apparatus (i.e., the remainder of the device). Figure 10 shows a chip carrier for electrically connecting the chip to the remainder of the system (column 15, lines 45-55). Heller et al also teach voltammetry to detect DNA hybridization (column 19, lines 15-42), which is interpreted as measuring and detecting the voltage applied between the common and measuring electrodes. Heller et al also teach fluid input ports (column 15, lines 39-45), and oligonucleotides (i.e., nucleic acids) attached to the electrode microlocations (column 4, lines 60-67).

It is noted that the courts have held that "while features of an apparatus may be recited either structurally or functionally, claims directed to an apparatus must be distinguished from the prior art in terms of structure rather than function." In re Schreiber, 128 F.3d 1473, 1477-78, 44 USPQ2d 1429, 1431-32 (Fed. Cir. 1997). In addition, "[A]pparatus claims cover what a device is, not what a device does." Hewlett-Packard Co. v. Bausch & Lomb Inc., 909 F.2d 1464, 1469, 15 USPQ2d 1525, 1528 (Fed. Cir. 1990) (emphasis in original). Therefore, the various uses recited in claim 1 (e.g., the entire recitation of the claim beginning with "when the chip" in line 17 to the end of the claim) fail to define additional structural elements to the device of claim 1. Because Heller et al the structural elements of claim 1, the claim is anticipated by Heller et al. See MPEP § 2114.

Regarding claim 7, Heller et al teach the chip of claim 1, wherein each of the microlocations, which are measuring electrodes, is connected with each of a plurality of wirings on a one to one basis; namely, Figure 3 (column 9, lines 52-64).

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Regarding claim 8, Heller et al teach the chip of claim 1, wherein the chip (i.e., the matrix hybridization region) is adapted for removal from the remainder of the device (column 6, lines 50-53), which is interpreted as being configured for insertion and removal from the measuring apparatus (i.e., the remainder of the device). Figure 10 shows a chip carrier for electrically connecting the chip to the remainder of the system (column 15, lines 45-55). Heller et al also teach voltammetry to detect DNA hybridization (column 19, lines 15-42), which is interpreted as measuring and detecting the voltage applied between the common and measuring electrodes

Regarding claim 9, Heller et al teach the chip of claim 1, wherein the chip forms part of a card; namely, the chip is a card that fits into the chip carrier of Figure 10 (column 15, lines 45-55).

Claim Rejections - 35 USC § 103

- 8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:
 - (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
- 9. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

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10. Claims 1-3 and 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Heller et al (U.S. Patent No. 5,632,957, issued 27 May 1997) in view of Wilding et al (U.S. Patent No. 5,587,128, issued 24 December 1996).

Regarding claims 2-3, Heller et al teach the detection chip of claim 1. In a single exemplary embodiment, Heller et al teach a body having a depression; namely, a APEX chip (i.e., an active programmable electronic matrix hybridization system) having depressed microlocations in wells of an array (column 7, line 65-column 8, line 17 and Figure 2A). Heller et al also teach a containment structure that fits over the chip (column 15, lines 39-45 and Figure 9), which is an upper cover fixed to the body of the chip over the depressions. Heller et al further teach the chip is enclosed within a containment vessel (column 15, lines 5-45 and Figure 9), which forms an enclosed internal space part. The microlocations within the chip in the containment vessel are addressable by nucleic acids (Abstract) from human genes that are analyzed (column 10, line 61-column 11, line 3); thus, the depression is capable of being filled and emptied of gene samples. The nucleic acid attached (i.e., immobilized) at each microlocation is different (column 4, lines 55-60).

Heller et al teach that each of the plurality of microlocations has an electrode (column 8, lines 1-17), which are measuring electrodes. Heller et al also teach Figure 2B, which shows a single individual microlocation bearing a positive charge and the other microlocations bearing negative charges (column 8, lines 53-65); thus, one microlocation functions as a common electrode which is a counter electrode to the remaining measuring electrodes, and all of the microlocations are arranged in an array in the space part. Figure 2B also shows the counter electrode is not in contact with the other electrodes because it is in a different well in the array. Heller et al also teach a measuring apparatus capable of detecting and analyzing genes; namely, the remainder of the system (Abstract) comprising a computer that measures currents, potentials, and results of assays (column 13, lines 1-4). Heller et al also teach voltammetry to detect DNA hybridization (column 19, lines 15-42), which is interpreted as measuring and detecting the voltage applied between the common and measuring electrodes.

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Heller et al also teach the chip (i.e., the matrix hybridization region) is adapted for removal from the remainder of the device (column 6, lines 50-53), which is interpreted as being configured for insertion and removal from the measuring apparatus (i.e., the remainder of the device). Figure 10 shows a chip carrier for electrically connecting the chip to the remainder of the system (column 15, lines 45-55). Heller et al also teach voltammetry to detect DNA hybridization (column 19, lines 15-42), which is interpreted as measuring and detecting the voltage applied between the common and measuring electrodes. Heller et al also teach fluid input ports (column 15, lines 39-45), and oligonucleotides (i.e., nucleic acids) attached to the electrode microlocations (column 4, lines 60-67).

It is noted that the courts have held that "while features of an apparatus may be recited either structurally or functionally, claims directed to an apparatus must be distinguished from the prior art in terms of structure rather than function." *In re Schreiber*, 128 F.3d 1473, 1477-78, 44 USPQ2d 1429, 1431-32 (Fed. Cir. 1997). In addition, "[A]pparatus claims cover what a device *is*, not what a device *does.*" *Hewlett-Packard Co. v. Bausch & Lomb Inc.*, 909 F.2d 1464, 1469, 15 USPQ2d 1525, 1528 (Fed. Cir. 1990) (emphasis in original). Therefore, the various <u>uses</u> recited in claim 1 (e.g., the entire recitation of the claim beginning with "when the chip" in line 17 to the end of the claim) fail to define additional structural elements to the device of claim 1. Because Heller et al the <u>structural</u> elements of claim 1, the claim is anticipated by Heller et al. See MPEP § 2114.

While Heller et al teach fluid inlet ports 137 of Figure 9 (column 15, lines 39-45), which are injection holes; Heller et al do not teach injection holes extending through the body and the cover into said depression.

However, Wilding et al teach a device for detecting polynucleotides by measuring conductivity (column 21, lines 15-20). The device of Wilding et al comprises a body having a depression (Figure 2B), an upper cover to be fixed to said body from above said depression (Figure 2B), an enclosed internal space part, formed by said depression in said body as a result of said upper cover being fixed to said body (e.g., the device is sealed by the cover; column 4, lines 15-20 and Figure 2B). Wilding et al also teach

Figure 1C, which shows injection holes 16 extending through cover 12 and into the channel 22, which is a depression in the body of the device (column 16, lines 25-46). Wilding et al also teach the added advantage that the ports allow addition of the sample and reagents and the withdrawal of products (column 16, lines 25-46) while maintaining a seal over the device (column 4, lines 16-24).

While Wilding et al do not specifically teach the injection holes on two opposing surface of each of said body and said upper cover, the courts have held that the rearrangement of parts within a device is obvious when the arrangement does not specifically modify the operation of the device (*In re Japikse*, 181 F.2d 1019, 86 USPQ 70 (CCPA 1950)). See MPEP §2144.04.

It would therefore have been obvious to a person of ordinary skill in the art at the time the claimed invention was made to have modified the chip of Heller et al with the injection holes extending through the body and the cover as taught by Wilding et al with a reasonable expectation of success. The ordinary artisan would have been motivated to make such a modification because said modification would have resulted in allowing addition of the sample and reagents and the withdrawal of products while maintaining a seal over the device as explicitly taught by Wilding et al (column 16, lines 25-46 and column 4, lines 16-24).

Regarding claim 3, the chip of claim 1 is discussed above. While Heller et al teach the cover has optical viewing ports (column 15, lines 39-45), Heller et al do not teach the cover is transparent.

However, Wilding et al teach a device for detecting polynucleotides by measuring conductivity (column 21, lines 15-20). The device of Wilding et al comprises a body having a depression (Figure 2B), an upper cover to be fixed to said body from above said depression (Figure 2B), an enclosed internal space part, formed by said depression in said body as a result of said upper cover being fixed to said body (e.g., the device is sealed by the cover; column 4, lines 15-20 and Figure 2B). Wilding et al also teach the device has a transparent cover which has the added advantage of allowing optical detection of agglutination of the hybridized polynucleotides (column 8, lines 56-65).

It would therefore have been obvious to a person of ordinary skill in the art at the time the claimed invention was made to have modified the chip of Heller et al with the transparent cover as taught by Wilding et al with a reasonable expectation of success. The ordinary artisan would have been motivated to make such a modification because said modification would have resulted in allowing optical detection of agglutination of the hybridized polynucleotides as explicitly taught by Wilding et al (column 8, lines 56-65).

Regarding claim 11, the chip of claim 1 is discussed above. Heller et al do not teach Peltier elements.

However, Wilding et al teach a device for detecting polynucleotides by measuring conductivity (column 21, lines 15-20). The device of Wilding et al comprises a body having a depression (Figure 2B), an upper cover to be fixed to said body from above said depression (Figure 2B), an enclosed internal space part, formed by said depression in said body as a result of said upper cover being fixed to said body (e.g., the device is sealed by the cover; column 4, lines 15-20 and Figure 2B). Wilding et al also teach the device has Peltier heating elements which provide the added advantage of providing both heating and cooling functions (column 17, lines 15-17).

It would therefore have been obvious to a person of ordinary skill in the art at the time the claimed invention was made to have modified the chip of Heller et al with the Peltier devices as taught by Wilding et al with a reasonable expectation of success. The ordinary artisan would have been motivated to make such a modification because said modification would have resulted in providing both heating and cooling functions as explicitly taught by Wilding et al (column 17, lines 15-17).

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct

from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

12. Claims 1-6, 8, and 11 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-5, 7, and 16-22 of U.S. Patent No. 6,916,614 in view of Wilding et al (U.S. Patent No. 5,587,128, issued 24 December 1996. Both sets of claims are drawn to chips having electrodes within depressions (i.e., the pin electrodes of the '614 claims are within a recess of a frame), counter-electrodes, immobilized nucleic acids, Peltier elements, and chips loaded into apparatuses. The claims of the '614 patent are silent with respect to covers and insertion of the chip into and removal from a measuring apparatus.

However, Wilding et al teach chips and apparatuses comprising: a body having a depression (Figure 2B) and an upper cover to be fixed to said body from above said depression (Figure 2B) with the added advantage that the cover seals the reaction chamber during reactions (column 4, lines 15-20). Wilding et al also teach the chip is inserted in an appliance for detecting the contents of the device (i.e., a measuring apparatus; column 19, lines 15-37 and Figures 17 and 18), having the added advantages that the movement of fluid samples are monitored by the appliance (column 19, lines 35-37) and that the presence of polynucleotides is detected by measuring conductivity (column 21, lines 15-20).

It would therefore have been obvious to a person of ordinary skill in the art at the time the invention was claimed to have modified the chips and apparatuses of the '614 claims with the cover and removability as taught by Wilding et al with a reasonable expectation of success. The ordinary artisan

would have been motivated to make such a modification because said modification would have resulted in sealing of the reaction chamber during reactions, monitoring of fluid samples and detection of polynucleotides by conductivity measurements as explicitly taught by Wilding et al (column 4, lines 15-20, column 19, lines 35-37, and column 21, lines 15-20).

This is a <u>provisional</u> obviousness-type double patenting rejection.

Response to Arguments

- 13. Applicant's arguments filed 12 October 2006 (i.e., the "Remarks") with respect to the rejection of the claims under 35 USC 102(b) as anticipated by Hollis et al and under 35 USC 103(a) an obvious over Wilding et al in view of Hollis et al have been considered but are moot in view of the new ground(s) of rejection.
- 14. Applicant argues on pages 7-9 of the Remarks that U.S. Patent No. 6,916,614 (i.e., Takenaka) does not disclose a chip that is configured to be inserted into and removed from a measuring apparatus capable of analyzing and detecting genes, and that, for example, the device of Takenaka does not place an electrolyte in the space part.

However, as noted above, Wilding et al do teach an insertable chip with a cover having the added advantages of reaction chamber during reactions, monitoring of fluid samples and detection of polynucleotides by conductivity measurements as explicitly taught by Wilding et al (column 4, lines 15-20, column 19, lines 35-37, and column 21, lines 15-20). Thus, the ordinary artisan would have been motivated to modify the chip of the '614 patent with the teachings of Wilding et al for the reasons cited above.

Applicant's additional arguments regarding placing of electrolytes, washing, etc have been considered but are moot because, as noted in the rejection of claim 1 under 35 USC 102(b), these limitations are drawn to intended uses of the chip rather than integrated structural limitations of the chip.

The combination of the claims of '614 patent in view of the teachings of Wilding et al teach all of the structural limitations of the instant claims, and the examined claims are thus obvious over the combination of '614 patent in view of Wilding et al.

Conclusion

- 15. No claim is allowed.
- 16. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, THIS ACTION IS MADE FINAL. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).
- 17. A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.
- 18. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert T. Crow whose telephone number is (571) 272-1113. The examiner can normally be reached on Monday through Friday from 8:00 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla can be reached on (571) 272-0735. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Robert T. Crow Examiner Art Unit 1634

RAM R. SHUKLA, PH.D. SUPERVISORY PATENT EXAMINER